IN THE UNITED STATES DISTRICT COURT
FOR MARYLAND

VIRGINIA E. BUCHANAN
SHERMAN T. BUCHANAN, SR.
1012 Fairway Avenue
Glen Burnie, Maryland 21061

Plaintiff

v.

MERCK & CO., INC.
One Merck Drive
Whitehouse Station, New Jersey 08889

And
PFIZER, INC.
235 East 42nd Street
New York, New York 10017

And
PHARMACIA CORP.
100 Route 206 North
Peapack, New Jersey, 07977

And
MONSANTO COMPANY
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

And
G.D. SEARLE, LLC
4901 Searle Parkway
Skokie, Illinois 60077

Defendants

Civil Action No.: AMD 07CV2505

COMPLAINT AND
DEMAND FOR JURY TRIAL

COMPLAINT

JURISDICTION

1. This case is brought pursuant to 28 U.S.C. § 1332(a) as there exists complete diversity of citizenship and the amount in controversy exceeds $75,000.00, exclusive of interest or costs.

2. Plaintiffs' claims accrued in whole or in part in Glen Burnie, Maryland. Plaintiffs Virginia E. Buchanan and Sherman T. Buchanan, Sr. are resident citizens of Glen Burnie, Maryland. Defendant is a domestic corporation that is currently, and has been at all pertinent times, engaged in business, directly or by authorized agent, in Glen Burnie, Maryland. Consequently, jurisdiction and venue are proper in this Court.

PARTIES

3. Plaintiffs Virginia E. Buchanan and Sherman T. Buchanan, Sr. are individuals residing at 1012 Fairway Avenue, Glen Burnie, Maryland 21061.

4. Defendant Merck & Co., Inc. (hereinafter "Merck"), was and is, a New Jersey corporation with its address and principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey. At all times relevant herein. Defendant was and is in the business of developing, manufacturing, promoting, marketing and distributing, and/or selling in interstate commerce and the State of Maryland, either directly or indirectly, pharmaceuticals and other products, including the product known as VIOXX® (rofecoxib) (hereinafter "Vioxx").

5. Defendant Pfizer, Inc. (hereinafter "Pfizer") is a Delaware corporation with its address and principal place of business at 235 East 42nd Street, New York, New York 10017. Defendant Pfizer, Inc. is authorized to do business and does do business in the State of Maryland. At all times relevant hereto, Pfizer was and is in the business of developing, manufacturing, promoting,

marketing and distributing, and/or selling in interstate commerce and the State of Maryland, either directly or indirectly, pharmaceuticals and other products, including the product known as CELEBREX® (celecoxib) (hereinafter "Celebrex").

6. Defendant Pharmacia Corporation (hereinafter "Pharmacia") is a Delaware corporation with its address and its principal place of business at 100 Route 206 North, Peapack, New Jersey, 07977. On July 16, 2002 Pfizer announced its proposed acquisition of Pharmacia Corporation (hereinafter "Pharmacia"). On April 16, 2003, Pfizer completed its $60 billion acquisition of Pharmacia. As a wholly-owned subsidiary of Pfizer, Pharmacia acted in all aspects as Pfizer's agent and alter ego. Pharmacia is authorized to do business and does business in the State of Maryland. At all times relevant hereto, Pharmacia was in the business of promoting, manufacturing, marketing, distributing, and/or selling in interstate commerce and the State of Maryland, either directly or indirectly, Celebrex.

7. Defendant Monsanto Company (hereinafter "Monsanto") was the parent corporation of Pharmacia and is a Delaware corporation with its principal place of business at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto is authorized to do business and does business in the State of Maryland. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of promoting, manufacturing, marketing, distributing, and/or selling in interstate commerce and the State of Maryland, either directly or indirectly, Celebrex.

8. Defendant G.D. Searle LLC (hereinafter "Searle") was a subsidiary of Pharmacia Corporation and is, upon information, knowledge and belief, an Illinois Corporation with its address and its principal place of business at 4901 Searle Parkway, Skokie, Illinois 60077. In April 2000, Searle was acquired by Pharmacia, and became a wholly-owned subsidiary of

Pharmacia. At the time of Pfizer's acquisition of Pharmacia, Searle was a wholly-owned subsidiary of Pharmacia, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of Pfizer. Searle is authorized to do business and does do business in the State of Maryland. At all times relevant hereto, Searle was in the business of promoting, manufacturing, marketing, distributing, and/or selling in interstate commerce and the State of Maryland, either directly or indirectly, Celebrex.

FACTS COMMON TO ALL COUNTS

9. This action arises from damages sustained by Plaintiffs which were caused by the pharmaceuticals VIOXX® and Celebrex®, ostearthritis and pain-relief drugs containing rofecoxib and celecoxib respectively. These drugs are COX-2 inhibitors and are members of a class of drugs known as non-steroidal anti-inflammatory drugs ("NSAIDS").

10. Vioxx and Celebrex are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings as to the dangers associated with their use.

11. Plaintiff, Virginia E. Buchanan, (hereinafter "Plaintiff") was provided with a prescription for Vioxx by her physician and consumed Vioxx in accordance with her physician's instructions from approximately December 2000 – September 2004.

12. Plaintiff was provided with a prescription for Celebrex by her physician and consumed Celebrex in accordance with her physician's instructions from approximately June 1999 – November 2000, and from October 2004 – March 2005.

13. As a result of the consumption of each of these drugs and/or the combination of the two, on or about March 22, 2005, Plaintiff suffered injuries, including but not limited to a stroke.

14. Defendant Merck was, at all times relevant hereto, engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing Vioxx.

15. Defendants Pfizer, Pharmacia, Monsanto, and Searle were, at all times relevant hereto, engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing Celebrex.

16. Defendants Merck, Pfizer, Pharmacia, Monsanto, and Searle (hereinafter "Defendants") sold Vioxx and Celebrex by misleading users about the products and by failing to adequately warn the public at large, including Virginia E. Buchanan, of the potential serious dangers which Defendants knew or should have known might result from consuming their products. Defendants widely and successfully marketed Vioxx and Celebrex through the United States, including to improper customers, by, among other things, conducting promotional campaigns, which misrepresented the efficacy of both Vioxx and Celebrex respectively in order to induce widespread use and consumption. Vioxx and Celebrex were represented to aid in relieving pain and discomfort of arthritis, osteoarthritis and related problems. Defendants made misrepresentations by means of aggressive marketing to the consuming public, although only available through prescription, through the use of media including, but not limited to print and television advertisements as well as statements contained in sales literature provided to Virginia E. Buchanan's prescribing physician.

17. Defendants failed to perform adequate testing that would have shown Vioxx and Celebrex caused serious side effects. Defendants also failed to provide warnings that would accurately reflect the serious side effects caused by Vioxx and Celebrex.

18. Prior to the manufacturing, sale, and distribution of Vioxx and Celebrex, Defendants had notice and knowledge from several sources that Vioxx and Celebrex presented substantial and unreasonable risks of harm to consumers.

19. Despite knowledge of the serious risks that Vioxx and Celebrex posed to consumers, Defendants intentionally proceeded with the manufacturing, sale and marketing of Vioxx and Celebrex. Defendants' conduct was therefore wanton and willful, and displayed a conscious disregard for Virginia E. Buchanan's safety, in particular, and the public in general, entitling her to exemplary damages.

20. However, at the time Plaintiff was given Vioxx and Celebrex, she was not warned or aware of the serious and debilitating health effects of taking Vioxx and Celebrex because no warnings were communicated to her or to her physician by Defendants.

21. Defendants acted with conscious and wanton disregard for the health and safety of Virginia E. Buchanan, in particular, and the public in general. Therefore, Plaintiff is entitled to an award of additional damages for the sake of example and for the purpose of punishing defendants for the conduct, in an amount sufficiently large to be an example to others and to deter defendants and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization and ratification of the offices, directors, managing agents and/or employees of defendants.

ALLEGATIONS SPECIFIC TO DEFENDANT MERCK

22. Defendant Merck obtained FDA approval for Vioxx, and began distribution and sale of Vioxx throughout the United States, in approximately May of 1999. Vioxx is a brand name used by Merck to market and distribute rofecoxib.

23. Defendant Merck distributed and sold Vioxx to consumers such as Plaintiff. Vioxx was approved for marketing based on information submitted by Defendant Merck to the United States Food & Drug Administration ("FDA") in its Application to Market a New Drug for Human Use ("NDA").

24. Despite knowledge of the relationship between Vioxx and cardiovascular-related adverse health effects gained in its clinical trials and post-marketing reports and studies, Merck promoted and marketed Vioxx as safe and effective for persons such as Plaintiff.

25. In the late 1980's and early 1990's, Merck was facing a business crisis, because patents on several of its best-selling drugs, including Vasotec, Prinivil, Mevacor, Pepcid, and Prilosec were expiring. Never had a pharmaceutical company faced the loss of so many million dollar patents at the same time. Merck management even feared Merck may not survive as a company.

26. On or about December 20, 1994, Merck filed its first Investigational New Drug Application (IND) with the FDA to conduct clinical trials of Vioxx in humans. The IND identified the intended use of the drug as the treatment of osteoarthritis and acute pain.

27. Defendant Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the FDA on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

28. Defendant Merck also submitted an Application to Market a New Drug for Human Use ("NDA") to the FDA on November 23, 1998, for rofecoxib of oral suspension, at doses of 12.5 mg/mL and 25 mg/mL, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

29. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the "NDA") for rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. Following FDA approval of Vioxx in May of 1999, Merck marketed Vioxx as a selective Cox-2 inhibitor, which unlike traditional NSAIDs, did not inhibit the production of Cox-1. Merck claimed that since Vioxx was the most selective inhibitor of Cox-2 on the market, it conferred the anti-inflammatory and analgesic benefits of traditional NSAIDs without the associated gastrointestinal toxicity. Accordingly, Merck asserted that Vioxx was the safest NSAID on the market.

30. As early as November 1996, years before FDA approval of Vioxx in May 1999, Merck recognized that unless taken in conjunction with aspirin, Vioxx posed a "substantial risk" of "significantly higher rates" of cardiovascular adverse events such as myocardial infarctions, strokes and transient ischemic attacks because, as a selective Cox-2 inhibitor, it lacked aspirin's "anti-platelet (i.e. anti-clotting) effect." In fact, early in the development program for Vioxx, to demonstrate that it selectively inhibited Cox-2, Merck used a platelet aggregation assay to assess the drug's effect on Cox-1. That research established that Vioxx did not affect thromboxane production or platelet aggregation because it did not inhibit Cox-1. In addition, a Merck-sponsored study found that Vioxx, unlike several other NSAIDs against which it was tested, had no appreciable anti-platelet effect (Protocol 061).

31. Two months later, in February 1997, Vioxx researcher Briggs Morrison conceded that "without Cox-1 inhibition you will get more thrombotic events and kill drug." Responding to this observation, Merck's Vice President of Clinical Research, Alise Reicin, complained:

> This is a no win situation. The relative risk of [adverse GI events with] even low dose aspirin is 2-4 fold. Yet the possibility of increased CV [cardiovascular] events is of great concern (I just can't wait to be the one to present those results to senior management!). What about the idea of excluding high-risk CV patients- i.e. those that have already had an MI, CABG, PTCA.? This may decrease the CV event rate so that the difference between the two groups would not be evident. The only problem would be – would we be able to recruit any patients?

32. By early 1998, Merck's own clinical investigators, based on findings from a Merck-sponsored study (Protocol 023), advised the company that by inhibiting Cox-2, Vioxx, at the cellular level of blood vessel linings, may alter the homeostatic balance between prostacyclin – a Cox-2 platelet inhibitor that dilates blood vessels – and thromboxane – a Cox-1 platelet activator that constricts blood vessels – such that it could provoke the creation of blood clots.

33. In December 1997, Merck appointed a "Task Force" to investigate the incidence of cardiovascular serious adverse events in the ongoing Vioxx clinical trials. The reason for the investigation was the unexpected early results of a yearly clinical trial which showed a decline in the levels of PGI-2, the most potent of all inhibitors of platelet aggregation, but no inhibition of systemic thromboxane, in the urinalysis of patients taking Vioxx. This imbalance triggered a concern for the potential for thrombotic events.

34. The Task Force agreed to investigate the incidence of thrombotic events by analyzing the ongoing osteoarthritis (OA) trials. Because the trials were still blinded as to treatment groups, it could not be determined whether the adverse events in the database had occurred in the Vioxx, placebo, or "compared-to" drug populations. Therefore, the Task Force designed a study in which cardiovascular events from all arms of the OA trials would be added together, and the

combined groups' incidence rate would be compared to placebo patients from trials of other Merck drugs. An expedited time frame was established for completion of the analysis, because of the rush to get Vioxx to market ahead of the competitors.

35. In January 1998, the analysis pursuant to the Task Force's plan showed a statistically significant increased relative risk of 2.16 for females in the Vioxx study versus the placebo group selected by Merck for comparison. These results constituted a clear signal of cardiovascular toxicity that should have triggered immediate investigation and concern. Instead, Merck made an after-the-fact claim that the placebo comparison group must have had an "atypically low" incidence of cardiovascular events, such that the higher rate in the Vioxx group was downplayed. Further, Merck changed the rules after the game had been played, by deciding to compare the rate in the Vioxx group to a so-called "background" rate, even though no such comparison was stated in the plan for the study. Merck intentionally chose an inappropriate "background" rate for comparison, from a published study of older patients at high risk for cardiovascular disease. Based upon the result of this comparison, Merck incorrectly dismissed the result as of no concern. Merck failed to disclose the results of this pre-marketing analysis, and instead has misrepresented that it had no indication of cardiovascular risk before Vioxx was marketed.

36. In or about 1998, six months before Merck filed its New Drug Application ("NDA") with the FDA, Merck's Scientific Advisory Board for the drug recommended that researchers "systematically collect data on cardiovascular (CV) events in all clinical trials" for Vioxx. In issuing this recommendation, the Board noted that some of its consultants were concerned that "[b]ased on data on PGI [prostaglandin] metabolism obtained for Vioxx, it is conceivable that Vioxx could disturb the [endothelium-platelet] interaction to favor platelet aggregation."

37. Merck chose to expose consumers to the significant adverse health risks of Vioxx despite its knowledge at product launch, and from post-marketing data thereafter, of these risks. These adverse effects were realized in Adverse Event Reports, in clinical trials where such events were adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch which showed statistically significant increases in adverse cardiovascular events among Vioxx users.

38. Merck concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for Merck. Safety concerns over hypertension, thrombosis, edema and/or cardiovascular events would have drastically impacted Merck's positioning in the market as compared to a competitor's drug, Celebrex (celecoxib), which was placed on the market approximately three (3) months prior to the launch of Vioxx.

39. Defendant Merck submitted a Supplemental New Drug Application (sNDA-007) with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the sNDA, Defendant Merck performed the Vioxx Gastrointestinal Outcome Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

40. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking Naproxen 1000 mg/day," and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

41. Merck excluded "high" cardiovascular risk patients from the VIGOR trial. On or about November 18, 1999, Merck's senior biostatistician, Deborah Shapiro, provided a tightly-controlled, highly confidential interim safety report to the VIGOR study's Data Safety and Monitoring Board ("DSMB"). The report showed that almost twice as many serious cardiovascular events were occurring among patients taking Vioxx as among those taking Naproxen.

42. In or about March of 2000, Merck released the results of the VIGOR study. The study data revealed, among other things, that Vioxx users suffered five times as many heart attacks than their Naproxen counterparts. In addition, serious cardiovascular events (including heart attacks, ischemic strokes, unstable angina, and sudden unexplained deaths) were reported for more than twice as many Vioxx patients, compared with Naproxen patients. Vioxx had exhibited a significantly greater cardiovascular toxicity than Naproxen within the first six weeks of the VIGOR study. Despite the results of the VIGOR study Merck failed to include in its Vioxx label a cardiovascular warning that Vioxx was contraindicated in high risk CV patients.

43. On March 9, 2000, shortly after completion of the VIGOR study, Edward M. Scolnick, former president of Merck Research laboratories, concluded that "the CV [cardiovascular] events are clearly there" and stated that Merck should be prepared to "make clear to the world" that Vioxx's cardiovascular toxicity "is a class effect" (i.e. an effect of the class of selective Cox-2 inhibitors) that is "mechanism based as we worried it was," and as some of the company's consultants had maintained.

44. In industry sponsored studies presented in June of 2000 at the XV European United League Against Rheumatism Congress "EULAR," an organization in which Merck is a member and corporate sponsor, it was shown that Vioxx use resulted in a statistically significant increase

in hypertension and edema. The study compared rofecoxib and celecoxib use among patients with osteoarthritis who used hypertensive medication. Merck did nothing to further accurately publish these findings, or warn consumers. Further, it denied the results with respect to hypertension in an article entitled, *Spin War Aside, Lessons Emerge From COX-2 Trials*, in August 2000, published in Pharmacy Today, the official publication of the American Pharmaceutical Association, in August, 2000, p. 3.

45. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced Merck's financial stability to the detriment of its consumers. As a result of Merck's scheme, it reaped more than $2 billion in profit in 2000 alone, and appropriated approximately a 23 percent share of the market. By 2003, worldwide sales of Vioxx reached 2.5 billion dollars (U.S.), following the most impressive global sales growth of any drug in history.

46. Merck continued to profit from its scheme by withholding information from Plaintiff and the health care industry generally. For example, in November of 2000, Merck caused the publication of the VIGOR study results in the New England Journal of Medicine and knowingly downplayed and/or withheld the severity of cardiovascular risks associated with Vioxx consumption over Naproxen consumption and the underlying data. Bombardier, C., et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients With Rheumatoid Arthritis*. New Eng. J. Med. 2000; 343: 1520-1528.

47. Merck knowingly downplayed and, in certain instances, withheld from publication, the severity of cardiovascular and cerebrovascular risks associated with Vioxx. In June of 2000, industry-sponsored studies presented at the European United League Against Rheumatism

("EULAR"), an organization in which Merck is a member and a corporate sponsor, showed that Vioxx use resulted in statistically significant increases in hypertension and myocardial infarctions. On or about August 29, 2001, the Journal of the American Medical Association (JAMA) published a peer-reviewed human epidemiological study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukherjee, et al. The study showed what Merck had concealed—that the relative risk of developing a serious cardiovascular adverse event (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Merck's VIGOR trial compared with patients using Naproxen, at a 95% confidence interval ranged from: 1) 2.2 for event-free survival analysis when comparing all cardiovascular events termed "serious" in an FDA medical reviewer's opinion; 2) 2.38 among those adjudicated to have serious thrombotic cardiovascular adverse events; and 3) 4.89 for developing serious cardiovascular events among aspirin-indicated patients who used rofecoxib. See, Mukherjee, D., et al., *Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors*. JAMA 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users. *Id*.

48. In the JAMA study, the authors set forth the theory that, "by decreasing PGI2 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PGI2, potentially leading to an increase in thrombotic cardiovascular events." *Id*. at 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor, "tips the balance of prostacyclin/thromboxane in favor of

thromboxane, leading to increased vascular and thrombotic events." Bing, R., Lomnicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events*? J.Am.Coll. Cardiol 39:3, Feb. 6, 2002. This biological plausibility is further supported by studies completed at the University of Pennsylvania. Cheng, Y., et al., *Role of Prostacyclin in the Cardiovascular Response to Thromboxane A 2*, Journal of Science, 296:539-541, Apr. 19, 2002. The conclusion from these studies is that because Vioxx inhibited Cox-2 without substantially inhibiting Cox-1, it, among other things, created a homeostatic imbalance that could result in increased aggregation of blood platelets or blood clotting and thereby substantially increase the risk of adverse cardiovascular and cerebrovascular events, including heart attacks – both clinically recognized and unrecognized – ischemic strokes, and other serious injuries. Merck had reason to know and did know of these serious adverse events in patients who ingested Vioxx.

49. Merck continued its denial of these risks in order to continue reaping massive profits at the expense of patient's health and lives. On or about May 22, 2001, Merck issued a press release through PR Newswire touting and "reconfirm[ing] the favorable cardiovascular safety profile of Vioxx." On or about August 23, 2001, the day after the JAMA article was published, Merck stated in another press release: "the Company stands behind the overall and cardiovascular safety profile of Vioxx." In responsive Merck-authored and sponsored reviews, Merck claimed that Naproxen had a cardioprotective effect which accounted for the cardiovascular risks among its Vioxx users. This was disputed by Merck's own employees, who published a pooled analysis in Circulation in October of 2001 and concluded that the data was insufficient to ascertain the cardiovascular benefits of Naproxen. *Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib*, Konstam, M.A., et al., Circulation, 104:2280-2288 (October 3, 2001). The article, authored by Dr. Marvin Konstam and various internal

Merck employees, is a post-hoc retrospective pooled analysis of Vioxx data only available through access to Merck's files. The study shows that the data crosses dosing intervals and has, as a primary basis, interim placebo data from Alzheimer testing at the lowest possible dose of Vioxx (12.5 mg) as compared to 50 mg in VIGOR. However, Table 7 reveals that, at 50 mg, compared to other NSAIDs, Merck's additional data showed a greater than doubling of the risk of cardiovascular disease. Furthermore, in January of 2002, an epidemiologic study by Vanderbilt University School of Medicine was published in The Lancet concluding that, based upon information previously available, there is an absence of a protective effect of Naproxen or other non-aspirin NSAIDs on risk of coronary heart disease. Ray, W., et al., *Non-Steroidal Anti-inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study*, Lancet, 359:118-123, Jan. 12, 2002. A follow-up research letter by Ray, et al. appeared in The Lancet on October 5, 2002 reiterating the cardiovascular risks of Vioxx and an inability to confirm any protective effect of Naproxen. In addition, Italian pharmacologist Carlo Patrono, one of Merck's own consultants and an expert in the platelet effects of cyclooxygenase-inhibiting drugs (whom Merck regarded as "the world's most respected and knowledgeable" scientist in his field), advised Merck in March 2000, that the dramatic cardiovascular effects observed in the VIGOR study could not be attributed plausibly to Naproxen for several reasons. Furthermore, on or about March 24, 2000, University of Pennsylvania pharmacologist Garrett Fitzgerald, then acting as a Merck consultant, advised Merck of a paper in press that included Naproxen among several NSAIDs which, in contrast to aspirin, had no significant effect on the incidence of first nonfatal myocardial infarctions in females in an epidemiological study.

50. On September 17, 2001, Thomas W. Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to

Raymond V. Gilmartin, President and CEO of Defendant Merck, relating to "promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets." A copy of this letter is attached as Exhibit "A" hereto.

51. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

> Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the competitor non-steroidal anti-inflammatory drug (NSAID), Naprosyn (Naproxen).

52. The FDA, in this Warning Letter, severely rebuked Merck's claims that Vioxx has a 'favorable safety profile':

> …your claim in the [May 22, 2001] press release that Vioxx has a 'favorable cardiovascular safety profile,' is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to Naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDS is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the Naproxen treatment group (46 events, 1.1%) in the VIGOR study. (Emphasis added.)

53. The Warning Letter delineated the following misrepresentations made in six promotional audio conferences presented on behalf of Merck by Peter Holt, M.D., which were moderated by Merck employees; in Merck press releases; and in oral representations made by Merck sales representatives to promote Vioxx. According to this warning letter:

a) Merck, its agents, employees and representatives minimized the rate of myocardial infarctions. For example, in a June 21, 2000 audioconference, Merck began the discussion of the myocardial infarction rates observed in the VIGOR study by stating, "when you looked at the MI rate, the rate was

different for the two groups. The MI rate for Vioxx was .4 percent and if you looked at the Naproxen arm it was .1 percent, so there was a reduction in the MI's in the Naproxen group." Merck offered what purported to be a scientific explanation, when, in fact, it was purely hypothetical. DDMAC wrote that, as Merck knew, it was misleading to assert: "that Vioxx does not increase the risk of [heart attacks] and that the VIGOR finding is consistent with Naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you [Merck] fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and there is another reasonable explanation, that Vioxx may have pro-thrombotic properties."

b) Merck knew that the promotional statement was false because the reason for the difference between the MI outcomes for the Vioxx users versus the Naproxen users had not yet been determined;

c) Merck carefully excluded from the promotional literature materially relevant information that Vioxx may have pro-thrombotic properties;

d) DDMAC reprimanded Merck for understating the role of myocardial infarctions. Merck had claimed that the MI rate was 0.2 percent for Naproxen and 0.1 percent for Vioxx, which was completely inaccurate. DDMAC wrote, "contrary to [Merck's] claim that there was a higher rate of MIs in the Naproxen group compared to the Vioxx group, the MI rate for Vioxx in this subpopulation was 12 MIs among 3877 patients (0.3%) as compared to 4 MIs among 3878 patients (0.1% for Naproxen).

e) DDMAC reprimanded Merck for falsely claiming that the MI rate associated with the use of Vioxx was 'basically the same as" the crude MI rate in the Celebrex study known as CLASS (Celebrex Long-Term Arthritis Safety Study);

f) DDMAC reprimanded Merck for misleading claims regarding the efficacy of Vioxx as compared to its competitor Celebrex. When publicly comparing the VIGOR study to the CLASS study, Merck failed to inform consumers that the patient populations in the two studies were extremely different. The VIGOR study excluded patients who had angina or congestive heart failure with symptoms that occurred at rest or with minimal activity as well as patients taking aspirin or other antiplatelet agents, all of which, if anything, should have made Vioxx appear to present less cardiovascular toxicity. The CLASS study did not exclude these patients, therefore, making it more likely that the CLASS trial included patients with a higher risk for myocardial infarctions prior to their ingestion of Celebrex. Nevertheless, Merck improperly compared the two studies to misrepresent that Vioxx was more effective and safer than Celebrex.

g) Merck failed to point out that the more affordable alternative, Naproxen, had been statistically proven to produce half as many myocardial infarctions as Vioxx. These misrepresentations and omissions were made not only at the promotional audio conferences in June of 2000, but also at the annual meeting of the American Society of Health-Systems Pharmacists ("ASHP") in Los Angeles, California, on June 3 through June 6, 2001;

h) DDMAC reprimanded Merck for making false statements about the risks of Vioxx therapy in patients who were taking warfarin. For example, at an audio conference on June 16, 2000, Merck stated: "…if you look at the thromboembolic agents, it's very clear that these selective COX-2 inhibitors [of which Vioxx is a member] have the benefit of not having platelet aggregation and bleeding time, and therefore, can be used safely in terms of post-op and with Coumadin." This statement is directly contradicted by the precaution in the Product Insert, reprinted in the Physicians Desk Reference ("PDR"), which states: "…in post-marketing experience, bleeding events have been reported, predominantly in the elderly, in association with increases in prothormbin time in patients receiving Vioxx concurrently with warfarin."

i) DDMAC rebuked Merck for its false and misleading marketing: "Merck's promotional audio conferences and sales representative presentations failed to present the serious and significant risks associated with Vioxx use. They failed to state that Vioxx is contraindicated in patients who have experienced asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDS.

54. In those marketing promotional presentations, Merck omitted the warning about the possibility of serious gastrointestinal toxicity occurring with the use of Vioxx, such as gastric bleeding, ulceration or perforation; Merck failed to state that Vioxx's Product Insert clearly defines precautions for use in patients with liver and kidney disease; failed to include information about patient populations in which Vioxx is not recommended such as women in late pregnancy; and failed to include information about Vioxx's most common adverse effects:

serious cardiovascular and cerebrovascular events such as myocardial infarctions and ischemic strokes.

55. The eight (8) page Warning Letter concludes:

"Conclusions and Requested Actions:"

> The promotional activities and materials described above minimize the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.
>
> Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001. This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:
>
> 1. Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
>
> 2. Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.
>
> 3. A written statement of your intent to comply with "1" and "2" above.

56. In October 2001, Merck learned of the publication of an article stating that there was a higher reporting rate for Vioxx compared to Celebrex, for adverse events relating to renal events and cardiovascular effects. Merck responded by conducting an internal analysis of reported adverse events for Vioxx and Celebrex. Merck's analysis showed a greater reporting rate of myocardial infarction, as well as congestive heart failure and related illnesses, for Vioxx in

comparison to Celebrex. Merck disregarded this signal of cardiovascular toxicity and failed to disclose it to the public. Instead, Merck blamed the result on an alleged discrepancy in the number of events entered into the regulatory database for the two drugs. As in the case of the Task Force Analysis of 1997 and the VIGOR study of 2000, Merck once again searched for and found a reason to exonerate Vioxx and keep it on the market.

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58. On April 11, 2002, the FDA approved a supplemental application for the use of Vioxx for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

59. The revised labeling further states, under "ADVERSE REACTIONS," that the administration of Vioxx 50 mg, was associated with a higher incidence of gastrointestinal symptoms.

> ***Clinical Studies in OA and RA with VIOXX 50 mg (Twice the highest dose recommended for chronic use)***
> In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as Vioxx 50 mg. Vioxx 50 mg QD was associated with a higher incidence of gastrointestinal symptoms (abdominal pain, epigastric pain, heartburn, nausea and vomiting), lower extremity edema, hypertension, serious* adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 mg (see DOSAGE AND ADMINISTRATION).

A copy of the revised labeling is attached as Exhibit "B" hereto. (Highlighting provided in FDA website version).

60. The "Dear Doctor" letter, approved in April 2002, in conjunction with the revisions to the Vioxx labeling, outlines the changes to the Vioxx labeling. A copy of the "Dear Doctor" letter is attached as Exhibit "C" hereto.

61. However, the revised "Patient Information" sheet issued April 2002, does not add any information about the results of the VIGOR study." A copy of the revised "Patient Information Sheet" is attached as Exhibit "D" hereto.

62. The "Patient Information" sheet is the only written document that is provided to a patient for whom Vioxx is prescribed.

63. Both the initial labeling and the revised labeling are ineffective because they do not properly advise physicians and patients of the potential gastrointestinal side effects of Vioxx and of the significant increased risk of cardiovascular adverse events.

64. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that Vioxx may cause serious gastrointestinal and cardiovascular side effects, Defendant Merck concealed and/or downplayed the dangers associated with Vioxx, and continued to market the drug in the United States and abroad. In its 2001 Annual Report, for example, Defendant Merck states:

> The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to *Vioxx*…The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

65. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, Defendant Merck fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, **VIOXX**, ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.
>
> "Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. **Vioxx**, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **Vioxx** has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, **Vioxx** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **Vioxx** achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter.
>
> A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which **Vioxx** reduced the risk of serious gastrointestinal complications by half compared to the NSAID Naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **Vioxx** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

66. Despite the foregoing, Defendant Merck continued to represent to consumers that Vioxx was safe, and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug. Defendant Merck has also downplayed any potential gastrointestinal

side effects of the drug, promoting it as safer and more efficacious than other medications approved for treatment of similar conditions.

67. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive direct-to-consumer advertising and physician sampling program. Defendant Merck wildly and successfully blitz-marketed Vioxx in the U.S. by undertaking an advertising campaign extolling the virtues of Vioxx in order to induce its widespread use. This direct-to-consumer marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and other health care providers and HMO's, and promotional materials provided directly to potential Vioxx users themselves. The advertising campaign as a whole sought to create the image, impression and belief that the use of Vioxx was safe, had fewer side-effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though Merck knew these representations were false. According to reports in the public press, Merck spent an estimated $45 million advertising Vioxx for a mere eight months in 2004. For the more than five years that Merck marketed Vioxx in the United States, it remained Merck's leading drug for control of acute pain and chronic pain associated with osteoarthritis, rheumatoid arthritis, migraine headaches and dysmenorrheal pain.

68. In the television advertising directed to consumers, Merck promoted Vioxx in the following widely-disseminated television advertisement featuring testimony from former Olympic skater Dorothy Hamill:

> It seems like only yesterday. When I started skating at 8 years old – I never thought I'd experience the thrill of winning a medal. With all the great memories has come another thing I thought I'd never experience – the pain of osteoarthritis.

> Vioxx is here, a prescription medicine for osteoarthritis pain. With one little pill a day, Vioxx can provide powerful super 25 hour….relief. Vioxx specifically targets only the Cox-2 enzyme. A key source of arthrtitis pain. [Superimpose "See our ad in Prevention"].
>
> People with allergic reactions such as asthma to aspirin – see our ad in Prevention – or other arthritis medicines should not take Vioxx. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor, if you have liver or kidney problems. For more information [superimpose] 1-888-36VIOXX] talk to your doctor about once daily Vioxx for the relief of osteoarthritis pain.
>
> Perhaps my biggest victory is to be able to plan my day around my life – and not my pain.
>
> [Superimpose: Your results may vary. Ask your doctor if Vioxx is right for you. Vioxx for every day victories].

69. Notably absent from this advertisement was any reference to the serious cardiovascular side-effects manifested in Merck's clinical trials of Vioxx.

70. In print advertisements, Merck advertised Vioxx by picturing Dorothy Hamill accompanying the statements:

> Along with the all the great memories has come something I thought I'd never experience – the pain of osteoarthritis.
>
> The advertisements continued:
>
> Vioxx is here. 24-hour relief of the most common type of arthritis pain, osteoarthritis.
>
> It isn't about going for a medal. Or feeling like a kid again. It's about controlling the pain that can keep you from doing everyday things. And Vioxx may help. Vioxx is a prescription medicine for osteoarthritis, the most common type of arthritis.
>
> ONE PILL – ALL DAY AND ALL NIGHT RELIEF.
>
> You take Vioxx only once a day. Just one little pill can relieve your pain all day and all night for a full 24 hours…
>
> VIOXX EFFECTIVELY REDUCED PAIN AND STIFFNESS

In clinical studies, one daily Vioxx effectively reduced pain and stiffness. So Vioxx can help make it easier for you to do the things you want to do. By going for a morning glide on the ice.

TAKE WITH OR WITHOUT FOOD

Vioxx doesn't need to be taken with food. So you don't have to worry about scheduling Vioxx around meals.

IMPORTANT INFORMATION ABOUT VIOXX

People with allergic reactions, such as asthma, to aspirin or other arthritis medicines should not take Vioxx. In rare cases, serious stomach problems, such as bleeding can occur without warning. Tell your doctor if you have liver or kidney problems, or are pregnant. Also, Vioxx should not be used by women in late pregnancy. Vioxx has been extensively studied in large clinical trials. Commonly reported side-effects include upper respiratory infection, diarrhea, nausea and high blood pressure. ASK YOUR DOCTOR OR HEALTHCARE PROFESSIONAL ABOUT VIOXX. CALL 1-800 9MERCK8 FOR MORE INFORMATION, OR VISIT VIOXX.COM. PLEASE SEE IMPORTANT ADDITIONAL INFORMATION BELOW.

71. These direct-to-consumer advertisements make absolutely no mention of Vioxx's association with cardiovascular or cerebrovascular disease, notwithstanding that Merck had reason to know and, in fact, did know that Vioxx was causally related to serious cerebrovascular and cardiovascular side-effects.

a. As a result of such marketing, Vioxx gained a significant market share in competition with Celebrex that Merck would not have gained if it had not suppressed information about Vioxx and/or made false representations of Vioxx's superiority and efficacy. In public statements to the press, Merck has estimated that 105 million U.S. prescriptions for Vioxx were written between May 1999 and August 2004. Based on this estimate, Merck has estimated that approximately 20 million patients have taken Vioxx in the U.S. since the launch of the drug in May of 1999. Sales of Vioxx soared to

> 2.5 billion dollars in 2003 alone on the strength of the biggest direct-to-consumer marketing campaign ever undertaken by a pharmaceutical company for a prescription medication.

72. Adverse events continued to occur because of Vioxx use, and Merck continued to deny Vioxx's dangers. According to the FDA Adverse Event Reporting System (ERS), through October 2003, almost 2,000 adverse cardiovascular events were experienced by Vioxx users, including myocardial infarctions, cardiac arrest and cardiac failures.

73. On October 30, 2002, the Wall Street Journal reported that another study, sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, confirmed an increased "risk of heart attacks in patients taking the pill [Vioxx]." According to the Wall Street Journal article, within the first 30 days of taking Vioxx, the risk of heart attack was increased 30% as compared to patients taking Celebrex.

74. In or about November 2003, Merck received preliminary results of a study it had commissioned, performed by Merck personnel and Alex Walker, an executive at the Ingenix unit of United Health Group. This study revealed a statistically significant, greater incidence of myocardial infarction or unstable angina pectoris associated with the use of Vioxx compared to the NSAIDs ibuproen or diclofenac. The risk did not vary significantly by duration, use or dose. Merck never revealed the existence, much less the results of the study, prior to its withdrawal of Vioxx from the market in late September 2004.

75. In August 2004, Health Day News quoted the FDA as finding "this and other studies cast serious doubt on the safety" of Vioxx and that Celebrex "may be safer."

76. However, shortly after the August 24, 2004 FDA statement, Peter S. Kim, President of Merck Research Laboratories was quoted as saying that Merck "strongly disagrees" with the

findings of this new study. On August 26, 2004, The Street.com reported: "Merck Thursday released a detailed critique questioning the study's significance."

77. On or about November 8, 1999, Merck submitted an IND application to the FDA to conduct clinical trials of Vioxx to pursue a claim that Vioxx was effective in preventing colon polyps and ultimately colon cancer. Merck undertook another clinical study called the Adenomatous Polyp Prevention on Vioxx ("APPROVe") trial of Vioxx, 25mg/day, to try and demonstrate the drug's effectiveness in preventing colon polyps. At its first meeting in or about January 2002, the External Safety Monitoring Board ("ESMB") for the APPROVe trial voiced concerns regarding "trends noted in serious adverse clinical events and in thrombotic events."

78. On or about September 17, 2004, the ESMB noted that "the trend for excess risk" for heart attacks and strokes "has continued to grow at each meeting over the last 1-2 years." Consequently, the ESMB recommended that patients participating in APPROVe be instructed to discontinue the study treatment. Merck abruptly discontinued the APPROVe study in mid-September 2004.

79. On or about September 27, 2004, Merck advised the FDA of the ESMB's recommendation. On or about September 28, 2004, Merck informed the FDA that it was withdrawing Vioxx from the market.

80. Merck has claimed since the release of the APPROVe results in September 2004 that the risk of heart attack and stroke did not appear until after subjects had taken Vioxx for more than 18 months, based on so-called "adjudicated" events. However, Merck has concealed from the public its internal analysis of "investigator reported" cardiovascular events, which showed that the Vioxx rate exceeded placebo throughout the entire period of the study.

81. Furthermore, Merck has concealed its internal analysis of such events showing a statistically significant increased risk for Vioxx versus placebo in the 0 to 18-month segment as well as the 19-36 month segment of the study. In a graph of the "Kaplan-Meier cumulative rate curves" for Vioxx versus placebo, the Vioxx curve begins to exceed the placebo curve after 2-3 months, and separates from the placebo incidence curve by an increasing margin for the remainder of the 36 month study. Merck's concealment of this data has been willful, intentional, and designed to minimize its potential liability to plaintiffs and the public.

82. The APPROVe study demonstrated that Vioxx doubled the risk of heart attack and stroke for consumers who had taken the drug for a period in excess of 18 months, as compared to subjects taking a placebo for the same period of time.

83. In APPROVe, the relative risk for cardiovascular events for Vioxx patients already at a heightened cardiovascular risk was particularly high. For example, Vioxx patients with a history of symptomatic atherosclerotic cardiovascular disease were approximately 9 ½ times more likely to suffer such events than their placebo counterparts, and those with a history of diabetes were approximately six times more likely to experience such events than patients in the placebo arm.

84. In March 2005, an article by Thal reported on exposure to Vioxx among patients in a trial related to Alzheimer's disease. The article reported that during a follow-up of patients for a median duration of approximately 29 weeks in the Vioxx group and 20 weeks in the placebo group, there were 17 deaths in the Vioxx group compared to only 5 in the placebo group. Twelve of those deaths (11 in the Vioxx group and 1 in the placebo group) occurred more than 48 weeks after treatment discontinuation. There were five fatal myocardial infarctions and two fatal cardiac arrests in the Vioxx group versus none in the placebo group for either of these adverse

events. The authors did not provide a statistical analysis of the data, but they are clearly a cause for concern that the effects of Vioxx on the cardiovascular system may continue long after discontinuation of drug exposure.

85. Defendant Merck misrepresented to Plaintiff and the health care industry the safety and effectiveness of Vioxx and/or concealed material information, including adverse information regarding the safety and effectiveness of Vioxx.

86. Defendant Merck made misrepresentations and actively concealed adverse information at a time when Defendant Merck knew, or should have known, that Vioxx had defects, dangers, and characteristics that were other than what Defendant Merck had represented to Plaintiff and the health care industry generally. Specifically, Defendant Merck misrepresented to and/or actively concealed from Plaintiff, the health care industry, and the consuming public that:

b. Vioxx had statistically significant increases in cardiovascular and cerebrovascular side effects, including without limitation thrombosis, myocardial infarction, stroke (and sudden onset death), which could result in serious injury or death;

c. There had been insufficient and/or company run studies regarding the safety and efficacy of Vioxx before and after its product launch;

d. Vioxx was not fully and adequately tested for the cardiovascular and cerebrovascular side effects at issue herein;

e. Other testing and studies showed the risk of (or actual serious adverse risks; and/or that there was a greatly increased risk of) such cardiovascular and cerebrovascular events and death; and that there was a confirmed

mechanism by which these thrombotic or cardiovascular events occurred as reported in the scientific literature.

87. These misrepresentations and/or active concealment were perpetuated directly and/or indirectly by Defendant Merck.

88. Defendant Merck knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiff would rely on them, leading to the use of Vioxx.

89. If Defendant Merck had not engaged in this conduct, consumers, such as the Plaintiff would have switched from Vioxx to safer products or refrained wholly from its use.

90. Plaintiff alleges that the Defendant Merck's marketing strategies, including, without limitation, the detail and sampling programs and direct-to-consumer advertising, targeted Plaintiff to induce her to use Vioxx. At the time the Defendant Merck distributed, manufactured and marketed Vioxx, Defendant Merck intended that Plaintiff would rely on the marketing, advertisements and product information propounded by it.

91. As a direct and proximate result of Defendant Merck's misconduct as set forth herein, Plaintiff Virginia E. Buchanan has had physical and mental pain and suffering, and has incurred medical expenses and other damages for which she is entitled to compensatory and/or punitive damages, as set forth herein.

ALLEGATIONS SPECIFIC TO DEFENDANTS

PFIZER, PHARMACIA, MONSANTO, AND SEARLE

92. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

93. Defendants Pfizer, Pharmacia, Monsanto, and Searle (hereinafter "the Celebrex Defendants") were, at all times relevant hereto, engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the pharmaceutical known as Celebrex.

94. Celecoxib was developed in 1986 by Searle and marketed jointly by Searle and Pfizer under the brand name Celebrex®. Searle was acquired by Pharmacia, which was then acquired by Pfizer, in part so that Pfizer could take control of Celebrex.

95. On June 29, 1998, Searle and Pfizer filed for FDA approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name Celebrex. The FDA granted preliminary approval of the new drug on December 31, 1998 for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of Celebrex for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

96. In late January 1999, following FDA approval, Pfizer publicly launched Celebrex, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. Pfizer's massive marketing campaign fraudulently and misleadingly depicted Celebrex as a much safer and more effective pain reliever than traditional NSAIDs. Celebrex Defendants and their representatives and agents misrepresented the safety profile of Celebrex to consumers, the medical community, healthcare providers, and third party payors.

97. The Celebrex Defendants sold Celebrex by misleading users about the product and by failing to adequately warn the public at large, including Virginia E. Buchanan, of the potential serious dangers which Celebrex Defendants knew or should have known might result from consuming their product. The Celebrex Defendants widely and successfully marketed Celebrex through the United States, including to improper customers, by, among other things, conducting promotional campaigns, which misrepresented the efficacy of Celebrex in order to induce widespread use and consumption. Celebrex was represented to aid in relieving pain and discomfort of arthritis, osteoarthritis and related problems. The Celebrex Defendants made misrepresentations by means of aggressive marketing to the consuming public, although only available through prescription, through the use of media including, but not limited to print and television advertisements as well as statements contained in sales literature provided to Virginia E. Buchanan's prescribing physician.

98. Defendants failed to perform adequate testing that would have shown Celebrex caused serious side effects. The Celebrex Defendants also failed to provide warnings that would accurately reflect the serious side effects caused by Celebrex.

99. Prior to the manufacturing, sale, and distribution of Celebrex, the Celebrex Defendants had notice and knowledge from several sources that Celebrex presented substantial and unreasonable risks of harm to consumers.

100. The potential for cardiovascular risk of selective COX-2 inhibitors was known to the Celebrex Defendants long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Celebrex, the Celebrex Defendants were aware that, by selectively inhibiting only the COX-2 enzyme, Celebrex altered the homeostatic balance between prostacylcin synthesis and thromboxane and